UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* DR. STEPHAN PORTER, et al.

Plaintiffs,

v.

VINTAGE PHARMACEUTICALS, LLC, *d/b/a* QUALITEST PHARMACEUTICALS; et al.

Defendants.

13 Civ. 1506 (DLC)

**JOINT STIPULATION OF DISMISSAL**

Pursuant to Federal Rule of Civil Procedure 41(a)(1), this is a Joint Stipulation of Dismissal by the State of New York, on behalf of the Plaintiff States[1], defendants Vintage Pharmaceuticals, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US), Inc., *d/b/a* Qualitest Pharmaceuticals; Generics Bidco I, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics Bidco II, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US Parent), Inc.; Generics International (US Holdco), Inc.; Generics International (US Midco), Inc.; Endo Health Solutions Inc., *f/k/a* Endo Pharmaceuticals Holdings, Inc.; and Endo Pharmaceuticals Inc. (collectively, "Qualitest" or the "Defendants"), and the *qui tam* relator Stephan Porter ("Relator") (together with the Plaintiff States and the Defendants, the "Settling Parties.")

RECITALS

WHEREAS, on or about December 15, 2015, the United States of America, represented by the Department of Justice's Southern District of New York (the "United States"), filed a Stipulation and Order of Settlement and Dismissal, resolving all federal claims against

[1] California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Hawaii, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, Wisconsin, and the District of Columbia (collectively, the "Plaintiff States").

Defendants in this action, which this Court so-ordered on December 16, 2015 (the "United States Stipulation").

WHEREAS, the Settling Parties now wish to resolve the remaining state supplemental claims in this action.

WHEREAS, all Plaintiff States (with the exception of Delaware, Colorado and the District of Columbia which reported no damages in this action) have entered into separate State Settlement Agreements with the Defendants to settle the remaining state claims associated with this action. A copy of the State of New York's agreement is attached as Exhibit A (the "NY Agreement").

WHEREAS, all Plaintiff States (including Delaware, Colorado, and the District of Columbia), agree to dismiss with prejudice all the state claims in this action.

WHEREAS, the undersigned attorneys for the State of New York expressly represent that they have authority from duly-authorized representatives of all the Plaintiff States to enter into this stipulation.

Pursuant to Federal Rules of Civil Procedure 41(a)(1)(A), the terms and conditions of the State Settlement Agreements, and by consent, the Settling Parties hereby stipulate to dismissing with prejudice all claims asserted on behalf of the Plaintiff States and the Relator against Defendants in this action except for Relator's claims for his reasonable expenses and attorneys' fees and costs from the Defendants pursuant to 31 U.S.C. § 3730(d) and analogous state law provisions.

*[Signature Page to Follow]*

Dated: New York, New York
February 11, 2016

**FOR THE STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, ILLINOIS, HAWAII, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, WISCONSIN, AND THE DISTRICT OF COLUMBIA**

ERIC T. SCHNEIDERMAN,
Attorney General of New York

By: _____

Jay Speers
Counsel
David G. Abrams
Special Assistant Attorney General
Office of the Attorney General
Medicaid Fraud Control Unit
Civil Enforcement Division
120 Broadway, 13th Fl.
New York, NY 10271
*Counsel for the State of New York*

558/3

Dated: Washington, D.C.
February ___, 2016

**FOR THE DEFENDANTS**

ARNOLD & PORTER LLP

By: _____
Jonathan L. Stern
David D. Fauvre
555 Twelfth Street, NW
Washington, D.C. 20004
*Counsel for the Defendants*

**FOR THE RELATOR**

McCABE RABIN, P.A.

By: _____ 2/10/16
Ryon McCabe
1601 Forum Place, Suite 505
West Palm Beach, FL 33401
*Counsel for Relator*

By: _____ 10 Feb 16
Stephan Porter
Relator

* * *

SO ORDERED:

_____
Date

_____
HON. DENISE L. COTE
UNITED STATES DISTRICT JUDGE

# Exhibit A

# STATE SETTLEMENT AGREEMENT

## I. PARTIES

This Settlement Agreement (the "Agreement") is entered into by and among the State of New York ("the State"), defendants Vintage Pharmaceuticals, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US), Inc., *d/b/a* Qualitest Pharmaceuticals; Generics Bidco I, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics Bidco II, LLC, *d/b/a* Qualitest Pharmaceuticals; Generics International (US Parent), Inc.; Generics International (US Holdco), Inc.; Generics International (US Midco), Inc.; Endo Health Solutions Inc., *f/k/a* Endo Pharmaceuticals Holdings, Inc.; and Endo Pharmaceuticals Inc. (collectively, "Qualitest" or the "Defendants"), (hereinafter collectively referred to as "the Parties").

## II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. At all relevant times, Defendants distributed, marketed and sold pharmaceutical products in the United States, including chewable multivitamin fluoride supplement tablets ("Qualitest Fluoride Tablets").

B. On March 6, 2013, Stephan Porter ("Relator") filed a *qui tam* action in the United States District Court for the Southern District of New York captioned *United States of America, et al., ex rel. Porter v. Qualitest Pharmaceuticals Inc.,* Case No. 13-CV-1506 (S.D.N.Y.)(hereinafter the "Civil Action").

C. Defendants have entered into a separate civil settlement agreement (the "Federal Settlement Agreement") with the United States of America (as that term is defined in the Federal Settlement Agreement) hereinafter referred to as the "United States."

D. The State contends that the defendants caused claims for payment to be submitted to the State's Medicaid Program (see 42 U.S.C. §§ 1396-1396(v)). Claims may be submitted to the State's Medicaid Program directly or through an intermediary, including through a managed care organization (MCO). The State further contends that MCOs are contractors with the State's Medicaid programs and the submission of claims for payment to an MCO constitutes the submission of claims to the State's Medicaid Program.

E. The State contends that it has certain civil and administrative causes of action against defendants for engaging in the following conduct (the "Covered Conduct"):

The State contends that from on or about October 1, 2007 to on or about August 31, 2013, Defendants violated federal and state false claims act statutes by marketing, selling, and distributing Qualitest Fluoride Tablets that contained less than 50% of the fluoride ion indicated in the labels and, thereby, caused the submissions of false claims to the state Medicaid Program. This conduct shall be referred to below as the "Covered Conduct".

F. The defendants admit to the facts as set forth in Exhibit A, attached to this agreement.

G. To avoid the delay, expense, inconvenience, and uncertainty of protracted litigation of these causes of action, the Parties mutually desire to reach a full and final settlement as set forth below.

## III. TERMS AND CONDITIONS

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants and obligations set forth in this Agreement, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. Defendants agree to pay to the United States and the Medicaid Participating States (as defined in sub-paragraph (c) below), collectively, the sum of $39,000,000.00, plus accrued interest on that amount of 2% per annum commencing on September 14, 2015 and continuing and including the day payment is made under this Agreement (collectively, the "Settlement Amount"). The Settlement Amount shall constitute a debt immediately due and owing to the United States and the Medicaid Participating States on the Effective Date of the Federal Settlement Agreement, and subject to the terms of this Agreement. The debt shall forever be discharged by payments to the United States and the Medicaid Participating States, under the following terms and conditions:

(a) The defendants shall pay to the United States the sum of $22,444,681.73 plus accrued interest on that amount at the rate of 2% per annum commencing on September 14, 2015 ("Federal Settlement Amount"). The Federal Settlement Amount shall be paid pursuant to the terms of the Federal Settlement Agreement.

(b) The defendants shall pay to the Medicaid Participating States the sum of $16,555,318.27 plus accrued interest on that amount at the rate of 2% per annum commencing on September 14, 2015, ("Medicaid State Settlement Amount"), subject to the non-participating state deduction provision of Sub-paragraph (d) below ("Medicaid Participating State Settlement Amount"), no later than fourteen (14) business days after the expiration of the 30 day opt-in period for Medicaid Participating States described in Sub-paragraph (c) below. The Medicaid Participating State Settlement Amount shall be paid by electronic funds transfer to the New York State Attorney General's National Global Settlement Account pursuant to written instructions from the State Negotiating Team ("State Team"), which written instructions shall be delivered to counsel for defendants.

(c) Defendants shall execute a State Settlement Agreement with any State that executes such an Agreement in the form to which the defendants and the State Team have agreed or in a form otherwise agreed to by the defendants and an individual State. The State shall constitute a Medicaid Participating State provided this Agreement is fully executed by the State and delivered to the defendants' attorneys within 30 days of receiving this Agreement. If this condition is not satisfied within 30 days, the defendants offer to resolve this matter with the individual State shall become null and void absent written agreement between counsel for the defendants and the State Team to extend the 30 day period.

(d) The total portion of the amount paid by the defendants in settlement for the Covered Conduct for the State is $5,045,549.38, consisting of a portion paid to the State under this Agreement and another portion paid to the United States as part of the Federal Settlement Agreement. The amount allocated to the State under this Agreement is the sum of $2,779,549.40, plus applicable interest (the "State Amount"). If the State does not execute this Agreement within 30 days of receiving this Settlement Agreement, the State Amount shall be deducted from the Medicaid State Settlement Amount and shall not be paid by the defendants absent written agreement between counsel for the defendants and the State Team to extend the time period for executing this Agreement.

2. The State agrees to dismiss with prejudice any state law claims which the State has the authority to dismiss currently pending against the defendants in State or Federal Courts for the Covered Conduct.

3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of defendants set forth in this Agreement, and conditioned upon receipt by the State of its share of the Medicaid State Settlement Amount, the State agrees to release

defendants, their predecessors and current and former parents, divisions, subsidiaries, affiliates, successors, transferees, heirs, and assigns, and their current and former directors, officers, and employees, individually and collectively (collectively, the "Endo Released Entities"), from any civil or administrative monetary cause of action that the State has for any claims submitted or caused to be submitted to the State Medicaid Program as a result of the Covered Conduct.

4. The State specifically does not release any person or entity from any of the following liabilities:

(a) any criminal, civil, or administrative liability arising under state revenue codes;

(b) any criminal liability not specifically released by this Agreement;

(c) any civil or administrative liability that any person or entity, including any Endo Released Entities, has or may have to the State or to individual consumers or state program payors under any statute, regulation or rule not expressly covered by the release in Paragraph 3 above, including but not limited to, any and all of the following claims: (i) State or federal antitrust violations; (ii) Claims involving unfair and/or deceptive acts and practices and/or violations of consumer protection laws;

(d) any liability to the State for any conduct other than the Covered Conduct;

(e) any liability based upon obligations created by this Agreement;

(f) except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusions from the State's Medicaid program;

(g) any liability for expressed or implied warranty claims or other claims for defective or deficient products and services provided by defendants other than the Covered Conduct;

(h) any liability based on a failure to deliver goods or services due other than the Covered Conduct.

5. Defendants waive and shall not assert any defenses they may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

6. In consideration of the obligations of the State set forth in this Agreement, Endo Released Entities waive and discharge the State, its agencies, employees, and agents from any causes of action (including attorneys' fees, costs, and expenses of every kind and however denominated) which the Endo Released Entities have against the State, its agencies, employees, and agents arising from the State's investigation and prosecution of the Covered Conduct.

7. The amount that defendants must pay to the State pursuant to Paragraph III.1. above will not be decreased as a result of the denial of any claims for payment now being withheld from payment by the State's Medicaid program, any MCO which may be under contract to the State Medicaid Program or any other state payor for the Covered Conduct; and defendants agree not to resubmit to the State's Medicaid program, any MCO which may be under contract to the State Medicaid Program, or any other state payor, any previously denied claims, which denials were based on the Covered Conduct, and agrees to withdraw the appeal of or not to appeal or cause the appeal of any such denials of claims.

8. Defendants shall not seek payment for any claims for reimbursement to the State's Medicaid Program covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors, and further shall not seek payment for any claims for reimbursement to any MCOs which may be under contract to the State's Medicaid Program and attributable in any way to the Covered Conduct, from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors.

9. Defendants expressly warrants that it has reviewed its financial condition and that it is currently solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment of the Settlement Amount and compliance with this Agreement.

10. The Parties each represent that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

11. Except as expressly provided to the contrary in this Agreement, each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Except as otherwise stated in this Agreement, this Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any liability against any other person or entity.

13. Nothing in this Agreement constitutes an agreement by the State concerning the characterization of the amounts paid hereunder for purposes of the State's revenue code.

14. In addition to all other payments and responsibilities under this Agreement, defendants agree to pay all reasonable expenses and travel costs of the State Team, including

reasonable consultant fees and expenses. Defendants will pay this amount by separate check made payable to the National Association of Medicaid Fraud Control Units, after the Medicaid Participating States execute their respective Agreements, or as otherwise agreed by the Parties.

15. This Agreement is governed by the laws of the State, and venue for addressing and resolving any and all disputes relating to this Agreement shall be the state courts of appropriate jurisdiction of the State.

16. The undersigned defendants' signatories represent and warrant that they are authorized as a result of appropriate corporate action to execute this Agreement. The undersigned State signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement on behalf of the State through their respective agencies and departments.

17. The Effective Date of this Agreement shall be the date of signature of the last signatory to this Agreement. Facsimiles of signatures shall constitute acceptable binding signatures for purposes of this Agreement.

18. This Agreement shall be binding on all successors, transferees, heirs, and assigns of the Parties.

19. This Agreement constitutes the complete agreement between the Parties with respect to this matter and shall not be amended except by written consent of the Parties.

20. This Agreement may be executed in counterparts, each of which shall constitute an original, and all of which shall constitute one and the same Agreement.

**STATE OF NEW YORK**

By: _____ Dated: 12/15/15

[Name] Amy Held
[Title] Acting Director, MFCU
OFFICE OF THE ATTORNEY GENERAL

**FOR THE DEFENDANTS**

Dated: Washington, D.C.
February 8, 2016

ARNOLD & PORTER LLP

By: _____

JONATHAN L. STERN
DAVID D. FAUVRE
555 Twelfth Street, NW
Washington, D.C. 20004
*Counsel for the Defendants*

Dated: Malvern, PA
February 1, 2016

ENDO HEALTH SOLUTIONS INC.

By: _____

RAJIV De SILVA
Chief Executive Officer

Dated: Malvern, PA
February 1, 2016

ENDO PHARMACEUTICALS INC.

By: _____

RAJIV De SILVA
Chief Executive Officer

Dated: Malvern, PA
February 1, 2016

VINTAGE PHARMACEUTICALS, LLC

By: _____

RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS INTERNATIONAL (US), INC.

By: _____

RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS BIDCO I, LLC

By: _____
RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS BIDCO II, LLC

By: _____
RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS INTERNATIONAL (US PARENT), INC.

By: _____
RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS INTERNATIONAL (US HOLDCO), INC.

By: _____
RAJIV De SILVA

Dated: Malvern, PA
February 1, 2016

GENERICS INTERNATIONAL (US MIDCO), INC.

By: _____
RAJIV De SILVA

# EXHIBIT A

Defendants admit, acknowledge, and accept responsibility for the following facts:

1. As stated in guidelines issued jointly in 1994 by the American Dental Association, the American Academy of Pediatrics, and the American Academy of Pediatric Dentistry Pediatricians (the "ADA-AAP Guidelines"), dentists and other healthcare providers prescribe fluoride supplements to children under age 16 to prevent dental caries, *i.e.*, tooth decay.
2. The ADA-AAP Guidelines recommended that children living in areas where water is not fluoridated, or is insufficiently fluoridated, be prescribed fluoride supplements containing fluoride ion in the amount of 0.25 mg/day, 0.5 mg/day, or 1.0 mg/day, depending on the age of the child and the level of local water fluoridation, to prevent dental caries.
3. From in or about 2007 to July 2013, certain Defendants, operating as Qualitest Pharmaceuticals or Vintage Pharmaceuticals, manufactured and sold fluoride supplement products in chewable tablet form with multivitamins ("Qualitest Fluoride Tablets").
4. Qualitest Fluoride Tablets could only be dispensed subject to a prescription.
5. State Medicaid programs covered Qualitest Fluoride Tablets dispensed to Medicaid-eligible children. Further, defendants knew that Medicaid was a significant source of coverage for Qualitest Fluoride Tablets because defendants regularly paid rebates for these products to Medicaid agencies.
6. The product labeling for Qualitest Fluoride Tablets included dosage information, which stated the supplements contained 1.0 mg, 0.5 mg, or 0.25 mg of fluoride, respectively. The Qualitest Fluoride Tablets product labeling also referenced the ADA-AAP Guidelines and stated that one of its 1.0 mg, 0.5 mg, and 0.25 mg tablets, respectively, should be taken daily by children who, according to the ADA-AAP Guidelines, should receive 1.0 mg, 0.5 mg, and 0.25 mg, respectively, of fluoride ion per day.
7. Defendants used sodium fluoride (chemically, 2.2 mg of sodium fluoride contains 1 mg of fluoride ion) as an ingredient to manufacture Qualitest Fluoride Tablets.
8. Instead of using 2.2 mg of sodium fluoride as input to manufacture the 1 mg Qualitest Fluoride Tablets, Defendants used only 1 mg of sodium fluoride. Similarly, instead of using 1.1 mg of sodium fluoride for the 0.5 mg tablet and 0.55 mg of sodium fluoride for the 0.25 mg tablet, Defendants used 0.5 mg of sodium fluoride and 0.25 of sodium fluoride, respectively.
9. The Qualitest Fluoride Tablets did not therefore contain 1.0 mg, 0.5 mg, and 0.25 mg of fluoride ion; rather, the 1.0 mg Qualitest Fluoride Tablet contained approximately 0.44 mg of fluoride ion, the 0.5 mg Qualitest Fluoride Tablet contained approximately 0.22 mg of fluoride ion, and the 0.25 mg Qualitest Fluoride Tablet contained approximately 0.11 mg of fluoride ion.
10. As a result, children that were prescribed Qualitest Fluoride Tablets in accordance with recommendations of the ADA-AAP Guidelines (taking into account the pertinent variables including fluoridation of drinking water and age) and consumed one Qualitest Fluoride Tablet per day, as the product labeling instructed, received in any given tablet approximately 44% of the fluoride ion recommended by the ADA-AAP Guidelines.